## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

**BAVARIAN NORDIC A/S** 

Plaintiff,

v.

C.A. No. 05-614 (SLR)

ACAMBIS INC. and ACAMBIS, PLC,

Defendants.

LETTER OF REQUEST (LETTER OF ROGATORY) FOR INTERNATIONAL JUDICIAL ASSISTANCE ADDRESSED TO THE AUSTRIAN FEDERAL MINISTRY OF JUSTICE

(COMPETENT AUTHORITY: DISTRICT COURT OF GAENSERNDORF)

1. SENDER:

Edward A. Pennington, Esq.

Robert C. Bertin, Esq.

Dr. Axel Spies, Rechtsanwalt Bingham McCutchen LLP 3000 K Street, NW Suite 300 Washington, DC 20007, USA Phone +1 (202) 373-6672 Email R.Bertin@bingham.com

2. CENTRAL AUTHORITY

**OF REQUESTED STATE:** Bundesministerium für Justiz

(Federal Ministry of Justice)

Museumstrasse 7 A 1070 Vienna (Wien)

Austria

3. PERSON TO WHOM THE EXECUTED REQUEST IS

TO BE RETURNED:

Edward A. Pennington, Esq.

Robert C. Bertin, Esq.

Dr. Axel Spies, Rechtsanwalt Bingham McCutchen LLP 3000 K Street, NW Suite 300 Washington, DC 20007, USA Phone +1 (202) 373-6672

Email R.Bertin@bingham.com

4. NOT APPLICABLE

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# THE UNDERSIGNED APPLICANT HAS THE HONOR TO SUBMIT THE FOLLOWING REQUESTS:

### 5a. REQUESTING JUDICIAL

**AUTHORITY:** 

United States District Court for the District of Delaware

("Court")

Sue L. Robinson, U.S. District Court Judge, Caleb Boggs

Federal Building 844 N. King Street

Wilmington, DE 19801USA

## 5b. TO THE COMPETENT

**AUTHORITY OF:** 

Foreign Process Section (Civil Matters)

Rechtshilfe in Zivilsachen Bezirksgericht Gänserndorf Dr. Wilhelm Exner Platz 3

A 2230 Gänserndorf

Austria

## 5c. NAME OF THE CASE AND ANY IDENTIFYING

NUMBER:

Bavarian Nordic A/S v. Acambis Inc. and Acambis plc

C.A. No. 05-614 (SLR)

## 6. NAMES OF AND ADDRESSES OF THE PARTIES AND THEIR REPRESENTATIVES:

### a) Plaintiff

Bavarian Nordic A/S (hereinafter "Bavarian Nordic")

Bøgeskovvej 9 DK-3490 Kvistgård

Denmark

### Represented by:

Edward A. Pennington Esq.

Robert C. Bertin, Esq.

Dr. Axel Spies, Rechtsanwalt Bingham McCutchen LLP 3000 K Street, NW Suite 300 Washington, DC 20007, USA

### Delaware counsel:

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John W. Shaw, Esquire YOUNG CONAWAY STARGATT & TAYLOR LLP The Brandywine Building, 17th Floor 1000 West Street Wilmington, DE 19801, USA

### b) Defendant

Acambis, plc (hereinafter "Acambis") Peterhouse Technology Park 100 Fulbourn Road Cambridge, CB1 9PT United Kingdom

### Represented by:

Eric S. Namrow, Esq. Venable, LLP 575 7th Street, NW Washington, DC 20004, USA

### Delaware counsel:

Mary B. Graham and James W. Parrett, Jr. MORRIS, NICHOLS, ARSHT & TUNNELL 1201 N. Market Street P.O. Box 1347 Wilmington, DE 19899-1347

### c) Third Party

BAXTER HEALTHCARE SA (hereinafter "Baxter") Hertistrasse 2 CH 8304 Wallisellen Switzerland

Austrian address:

BAXTER Vertriebs GmbH, Wien Landstraßer Hauptstraße 99 A-1030 Wien, Austria

### Represented in the United States by:

April E. Abele, Esq.

TOWNSEND AND TOWNSEND AND CREW LLP Two Embarcadero Center Eighth Floor San Francisco, CA 94111-3834, USA

### NATURE AND PURPOSE OF THE PROCEEDINGS AND SUMMARY OF THE 7. **FACTS:**

The Court seeks assistance in obtaining evidence from Dr. Falko-Günter Falkner, resident of Orth/Donau, Austria, in a civil proceeding pending at this Court. The Plaintiff's complaint in this case was filed on August 19, 2005 the Defendants' Answer was served on September 8, 2005. Plaintiff's first set of interrogatories were served upon the Defendants on November 23, 2005. Defendants' answers to the Plaintiff's first set of interrogatories were served on the Plaintiff on December 22, 2005. Defendants' first set of interrogatories were served upon the Plaintiff on January 17, 2006. Defendants' answers to Plaintiff's second set of interrogatories were served on the Plaintiff on February 20, 2006.

### **(1)** Background

Beginning in 1996, Bavarian Nordic, the Plaintiff, sought to develop a new generation of smallpox vaccines that would be safer and more effective for individuals for whom the traditional smallpox vaccine is more dangerous, such as patients with disorders of the immune system, skin conditions such as eczema, or other disorders presenting a high risk of complications from existing smallpox vaccines. Through an extensive research and development, Bavarian Nordic developed a smallpox vaccine, modified vaccinia Ankara - MVA-BN®.

Bavarian Nordic owns several U.S. patents and pending patent applications directed to MVA-based vaccines, for example, U.S. Patent Nos. 6,761,893 and 6,913,752 cover the MVA-BN® virus and derivatives thereof.

#### **(2)** Claims

Bavarian Nordic alleges that Acambis obtained samples of vaccinia virus MVA from Professor Anton Mayr, a German scientist, that were exclusively licensed to Bavarian Nordic in 1996 for the development of MVA-BN®, and used these

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It further alleges that Acambis had never been involved in the development of MVA-based vaccines before Bavarian Nordic shared with Acambis its proprietary technology.

Bavarian Nordic also alleges that Acambis has committed tortious conversion regarding the virus samples it has received, misappropriation of trade secrets, unfair trade practices, in particular under the United States Lanham (Trademark) Act of 1947, as amended (15 United States Code § 1051 et seq.).

### (3) Status of the Proceeding

The proceeding at the Court is ongoing. By Court Order of October 26, 2005, the Court granted Plaintiff discovery on tortious conversion, trade secret misappropriation, alleged unfair trade practices, unfair competition, and the relationship between Acambis plc. and Acambis Inc and damages. All fact discovery must be completed by August 14, 2006. A pretrial conference will be held at the Court on May 8, 2007 with jury trial commencing on June 5, 2007.

### (4) Relevance of the Testimony

Dr. Falkner has been the director research and development for vaccines of Baxter Healthcare SA for presumably eight years. He has worked with MVA viruses for more than 10 years. In his earlier career, Dr. Falkner worked as a researcher as the US National Institutes of Health for approximately 2 years. Dr. Falkner was closely involved in the development and production of ACAM3000, in particular, as a member of the MVA project team and Director of Research and Development of Baxter Healthcare SA, and has extensive knowledge about the case, Acambis' Intellectual Property, Bavarian Nordic's Intellectual Property position, the patented processes that Acambis has used in the development and manufacture of MVA, the relationship of Acambis with the National Institutes of Health ("NIH") and the MVA strains that the NIH and Baxter provided to Acambis.

Therefore, the Court seeks assistance for this ongoing proceeding via this letter of request.

- 5 -DB02:5432865.1 064417.1001 All requests have a direct and necessary link with this ongoing proceeding against Acambis pending at the Court.

## 8. EVIDENCE TO BE OBTAINED OR OTHER JUDICIAL ACT TO BE PERFORMED:

The Court seeks the Austrian District Court, through the Federal Ministry of Justice, for an order that Dr. Falko-Günter Falker present himself for purposes of deposition upon oral examination at the following address of the District Court:

Bezirksgericht Gänserndorf Dr. Wilhelm Exner Platz 3 A 2230 Gänserndorf Austria.

or any other location that the District Court deems appropriate.

The Court requests that the US representatives be notified of the date, time and place of the examination duly in advance.

The Court would appreciate a copy of the report of Dr. Falkner's deposition by August 14, 2006, the deadline for the fact discovery.

### 9. IDENTITY AND ADDRESS OF ANY PERSON TO BE EXAMINED:

Dr. Falko-Günter Falkner
Director Research and Development
Baxter

Residence address: Neusiedlzeile 76a A 2304 Orth/Donau Austria

# 10. QUESTIONS TO BE PUT TO THE PERSONS TO BE EXAMINED OR STATEMENT OF THE SUBJECT-MATTER ABOUT WHICH THEY ARE TO BE EXAMINED:

The judge or the attorneys of the Plaintiff shall ask the witness questions, to the full extent allowed under Austrian procedural law, pertaining to the topics and questions listed in Attachment A.

### 11. DOCUMENTS OR OTHER PROPERTY TO BE INSPECTED:

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Currently, no documents and things are requested to be produced by Dr. Falkner.

# 12. ANY REQUIREMENT THAT THE EVIDENCE BE GIVEN ON OATH OR AFFIRMATION AND ANY SPECIAL FORM TO BE USED (ARTICLE 3(H)):

The evidence shall be given under oath and the deposition shall be overseen by an Austrian judge as the requested District Court deems appropriate.

### 13. SPECIAL METHODS OR PROCEDURE TO BE FOLLOWED:

It is requested that the Plaintiff's legal representatives and Dr. Falkner's legal representatives (if any) be permitted to examine of Dr. Falkner in Austria under the supervision of the judge. The Plaintiff's attorneys are familiar with the relevant events and the transactions in this complex matter. Accordingly, they will be able to elicit the relevant testimony in a manner as efficient and expeditious as possible. In addition, permitting the Plaintiff's attorneys to conduct the examination of Dr. Falkner will avoid the unnecessary waste of costs and attorneys fees for both parties in instructing Austrian counsel on the substance of the case.

In the event that the evidence cannot be taken in the manner requested, it is requested that the evidence be taken in the manner provided by the applicable law of the Republic of Austria for the formal taking of evidence.

(b) If production of any document by Dr. Falkner is withheld, in whole or in part, on the basis of a claim of privilege or that it contains attorney work product, each withheld document shall be separately identified in a privileged document list. The privileged document list must identify each document separately, specifying for each document at least the following information: (1) the title and type of document being withheld; (2) the date of the document; (3) the number of pages in the document; (4) the author(s), addressee(s); and recipient(s), identifying each by name, title, employer, job title, and business telephone number; (5) the subject matter of the document; (6) the specific pages or portions of the document being withheld; and (7) the specific privilege or claim being. invoked. If the author/sender, addressee or recipient is an attorney or foreign patent agent, he or she shall be so identified. The party asserting the privilege or hearing preparation claim also must provide a certification that all necessary elements of the asserted privilege/hearing

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preparation claim have been met and not waived with respect to each document.

# 14. REQUEST FOR NOTIFICATION OF THE TIME AND PLACE FOR THE EXECUTION OF THE REQUEST AND IDENTITY AND ADDRESS OF ANY PERSON TO BE NOTIFIED:

The Court wishes that the examination be recorded and to be informed of the time when, and the place where, the execution of the request will take place. This information shall be sent directly to the parties' representatives, as listed above, with a copy to the Court.

15. THE FEES AND COSTS INCURRED BY THIS PROCEDURE WILL BE BORNE BY:

Bingham McCutchen LLP Att. Robert C. Bertin, Esq. 3000 K Street, NW Suite 300 Washington, DC 20007, USA Phone +1 (202) 373-6672 Email R.Bertin@bingham.com

IN WITNESS WHEREOF the undersigned administrative judge of the Court has hereunto set his hand and caused the seal of said Court to be affixed at Wilmington, Delaware on this \_\_\_\_\_\_\_\_, 2006.

The Honorable Stee L. Robinson

Chief Judge

United States District Court for the District of Delaware

844 N. King Street

Wilmington, Delaware

United States of America

**ENCLOSURE: ATTACHMENT A: Questionnaire** 

# UNITED STATES DISTICT COURT FOR THE DISTRICT OF DELAWARE LETTER OF REQUEST IN THE MATTER C.A. NO 05-614 (SLR)

### Attachment A

### QUESTIONNAIRE

By authority of Rule 28(b) of the Federal Rules of Civil Procedure of the United States, Plaintiff Bavarian Nordic A/S ("Bavarian Nordic") hereby requests Dr. Falko-Günter Falkner on behalf of Baxter to answer questions related to a proceeding involving Bavarian Nordic and Acambis.

Illustrative questions are presented below to exemplify the type of questions and topics expected to be the subject of examination:

Note: This list of topics and questions is illustrative in nature and is not exhaustive.

## Topic 1: Communications<sup>1</sup> with Acambis<sup>2</sup> and NIH<sup>3</sup> regarding Manufacturing MVA3000<sup>4</sup>

- 1. Describe Baxter's role with respect to the June 12, 2002 meeting between Bavarian Nordic and Acambis and further describe Baxter's interest to participate in that meeting and its reasons thereto.
- 2. Describe any pre and post communication to the June 12, 2002 meeting with Acambis and NIH on the subject of Bavarian Nordic's manufacturing process.
- 3. Describe communications with Acambis and NIH on the subject of manufacturing MVA3000, and in particular on the development of the manufacturing process.
- 4. Describe all communications with Acambis and NIH regarding manufacturing MVA3000 using a serum free process.

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<sup>&</sup>quot;Communication" or "Communications" means any type of oral, written, magnetic, electronic, or visual contact(s) between two or more persons in which information, facts, statements, conversations, or opinions were exchanged, imparted, or received.

<sup>&</sup>quot;Acambis" means Acambis plc, Acambis Inc., and/or any corporate predecessor, any joint venture to which it is or was a party, any past or present division, department, parent, subsidiary, affiliate, director, officer, principal, agent, employee, consultant, representative, or other person acting on its behalf or under its control

The term "NIH" refers to the US National Institutes of Health.

<sup>&</sup>lt;sup>4</sup> "MVA" shall mean modified vaccinia Ankara; "MVA3000" refers to itself and/or ACAM3000.

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5. Describe Baxter's<sup>5</sup> current manufacturing process, including the types of chicken embryo cells used to manufacture MVA3000 at any time.

## Topic 2: Communications with Acambis and NIH regarding ownership and/or commercialization rights in MVA including MVA-572<sup>6</sup>

- 6. Describe all communications with Acambis and NIH on the subject of ownership and/or commercialization rights in MVA, including MVA-M4 and Therion's MVA-TBC.
- 7. Describe all communications with Acambis and NIH on the subject of ownership and/or commercialization rights in MVA-572.
- 8. Describe any due diligence performed by Baxter on the rights of Prof. Anton Mayr and Bayarian Nordic in MVA-572.
- 9. Describe the decision process and the reasons for why Baxter proceeded to manufacture MVA3000 based on MVA-572 without a license in view of Prof. Anton Mayr's and Bavarian Nordic's rights in the virus.
- 10. Describe communications, including with Prof. Anton Mayr relating to how Baxter first acquired MVA used to make Baxter's MVA-M4.<sup>7</sup>
- 11. Describe the decision process and the reasons for why Baxter did not use MVA-M4 as the starting material for MVA-3000.

### Topic 3: Communications with and Consulting Relationship with Dr. Carroll.

- 12. Describe the dates of each period during which Dr. Carroll was engaged as a consultant by Baxter.
- 13. For each period identified in 11, describe the subject matter of Dr. Carroll's consulting.
- 14. Describe all documents provided to or received from Dr. Carroll.
- 15. Describe all communications and meetings involving Dr. Carroll and any personnel at Baxter, including you, Mrs. Inles, Dr. Antoine, Dr. Dorner, Schleifinger, or Dr. Mundt.
- 16. Describe all technical information provided to Dr. Carroll since August 2005.

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<sup>&</sup>lt;sup>5</sup> "Baxter" refers to Baxter Healthcare SA and its subsidiaries, in particular in Austria.

<sup>&</sup>quot;MVA-572" refers to MVA designated 572.FHE.-22.02.1974, its progeny, and/or its derivatives, including that which was plaque purified by Dr. Bernard Moss of NIAID

MVA-M4 is a vaccine is derived from MVA-575 by plaque purification. MVA-M4 is not on deposit and, as such, has not been tested during the course of this litigation.

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## UNITED STATES DISTICT COURT FOR THE DISTRICT OF DELAWARE LETTER OF REQUEST IN THE MATTER C.A. NO 05-614 (SLR)

17. Describe all communications with Dr. Carroll since August 2005.

## Topic 4: Communications and data regarding safety and efficacy of MVA, including the Vivacs Reports and the MVA-M4.

- 18. Describe all experiments conducted by Baxter or Vivacs<sup>8</sup> on MVA to determine safety or efficacy.
- 19. Describe all communication with Acambis, Vivacs and/or Dr. Carroll with respect to the Vivacs Reports I, II and III.
- 20. Describe all communication and data produced by Baxter, or on its behalf, or otherwise known to Baxter regarding the replication characteristics of MVA-M4, including any communication thereof with Acambis, Vivacs and/or Dr. Carroll.

### Topic 5: Communications and data regarding the Antoine sequence.

21. Describe the decision process and all communication with Acambis, Vivacs and/or Dr. Carroll with respect to the resequencing of the five nucleotides purportedly being sequence errors in the so called Antoine sequence.

### Topic 6: Communications regarding European proceedings.

- Describe all communication with Acambis and/or Dr. Carroll with regard to Baxter's opposition and/or Acambis' opposition filed at the European Patent Office ("EPO") with respect to EP 1,335,987.
- Describe all communication with Acambis and/or Dr. Carroll relating to Baxter's decision to join the Austrian proceeding as an interested party and its role in that proceeding, including communications and meetings regarding the merits of the U.S. litigations.

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<sup>&</sup>lt;sup>8</sup> "Vivacs" refers to Vivacs GmbH, Martinsried, Germany, and its affiliates.